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[54] MESH COMPOSITE GRAFT

[75] Inventors: Leonard Pinchuk; John B. Martin, Jr., both of Miami; Bruce A. Weber, Pembroke Pines, all of Fla.

[73] Assignee: Corvita Corporation, Miami, Fla.

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[52] U.S. Cl. 623/1; 623/11; 623/12

[58] Field of Search 623/12, 1

[56] References Cited

U.S. PATENT DOCUMENTS

4,475,972 10/1984 Wong .

4,969,896 11/1990 Shors 623/1

Primary Examiner—David Isabella

Assistant Examiner—Debra S. Brittingham

Attorney, Agent, or Firm—Lockwood, Alex, FitzGibbon & Cummings

[57] ABSTRACT

A mesh composite graft including an inner component, an outer component formed from strands of durable material, such as polyethylene terephthalate, and an intermediate component made from strands of bicompatible synthetic material having a melting point less than that of the durable material from which the outer component is formed and less than that of the biocompatible synthetic material from which the inner component of the graft is formed. By heating the graft to a temperature grater than the melting point of the material from which the intermediate component is formed but less than the melting point of the outer component material and less than the melting point of the material from which the inner component is formed, the components are bound by the melted intermediate component to provide a totally porous, compliant composite graft reinforced by the outer component.

19 Claims, 1 Drawing Sheet

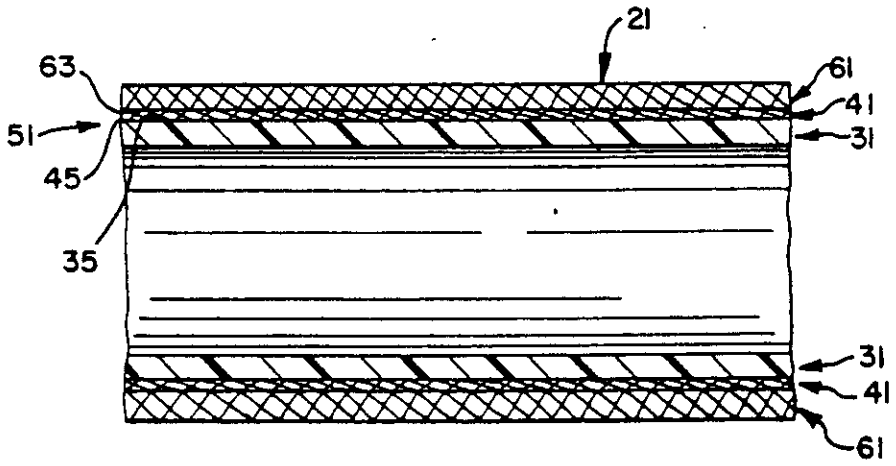


FIG. 1

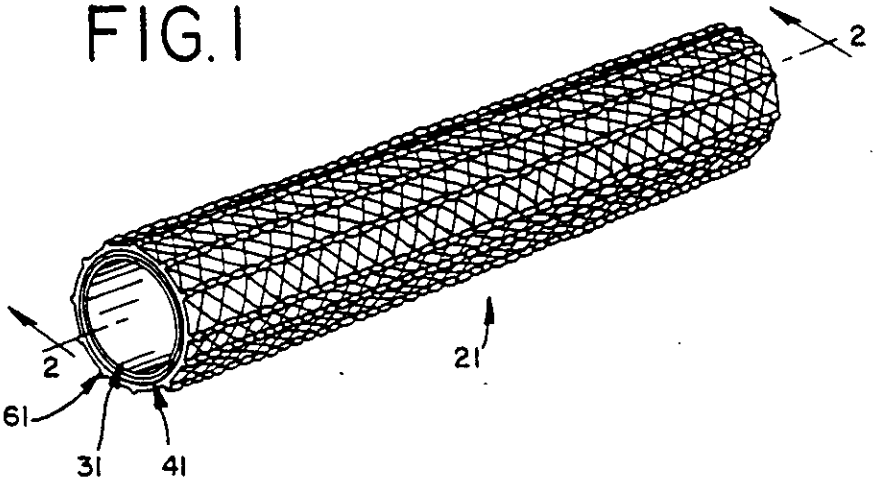
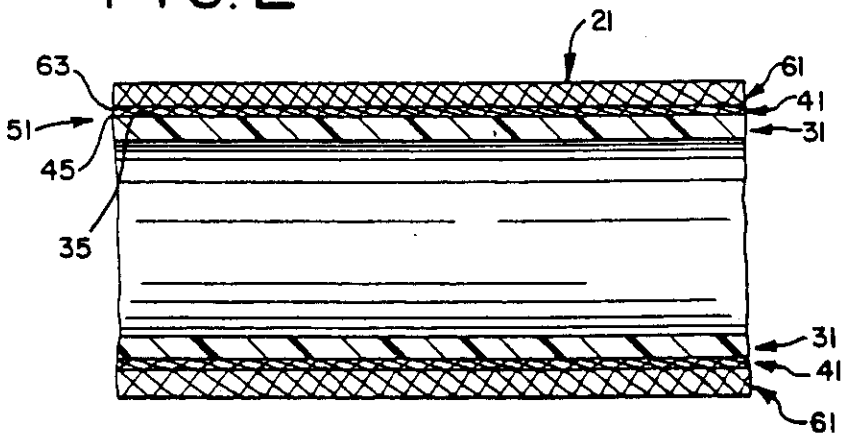


FIG. 2



MESH COMPOSITE GRAFT

BACKGROUND AND DESCRIPTION OF THE INVENTION

The present invention generally relates to implantable prostheses and the like and to methods for making same. More particularly, the invention relates to a graft, such as a vascular graft or AV-shunt, having a compliant porous inner component and a compliant porous load-bearing outer component, bound together by a porous intermediate component that is made of material having a melting point lower than that of the materials from which the inner and outer components are made. With the outer component bound by the intermediate component to the inner component, a porous, yet strengthened integral graft results.

Blood vessels are not straight, rigid tubes but elastic conduits made of a variety of materials and having a compliance that varies with functional considerations. For example, the venous system functions, in part, as the blood reservoir for the body. In order to be able to respond to a larger volume of blood sent into the system because of, for example, a change in arterial blood pressure, the vessels of the venous system must be sufficiently compliant so that they can distend. The arterial system functions as the body's pressure reservoir. In order to avoid the wide swings in the blood pressure and flow that are possible with every contraction and relaxation of the heart, yet be able to maintain sufficient blood pressure so that blood can be pushed into all regions of the body, including through the small-diameter arterioles and the microcirculatory bed, the arteries must have sufficient compliant strength to elastically expand and recoil without the marked distension of the venous system.

Conventional grafts, however, are generally made of materials and in shapes that provide a structure whose compliance is markedly different from that of the walls of the vessel to which they may be attached. Grafts having walls less compliant than that of the host vessel walls are problematic in that conditions, such as intimal hyperplasia and stenotic narrowing, may develop. Grafts with walls having greater compliance than that of the vessel to which the graft is attached are problematic in that a portion of the graft wall may balloon—that is, develop an aneurysm—after implantation.

Other known grafts, while they may be compliant, may not necessarily be made from biocompatible materials. The implantation of a graft made from such material may prompt a thrombogenic or immunological response with the resultant deleterious formation of microthrombi or microocclusions in and around the graft. Other grafts are made from generally non-porous materials, that, accordingly, do not facilitate the ingrowth of cells and tissue within the graft. The full incorporation of the graft into the surrounding host tissue is thereby frustrated. Still other conventional grafts are made from microporous textiles that require preclotting of the vessel wall with blood to prevent leakage of blood at implantation.

A demand therefore is present for an integral graft made from biocompatible materials and having a structure that has compliant strength similar to that of natural tissue but that is sufficiently porous so that the graft may become incorporated into the host tissue yet not leak blood. The present invention satisfies the demand.

The present invention includes a three component system, an inner component, an intermediate component, and an outer component. While the components may be made from materials having generally different melting points and different mechanical properties, at a minimum the inner component and outer component are made from a material or materials having a melting temperature higher than the material from which the intermediate component is made. More specifically, the inner component is porous and is made from a biocompatible synthetic material, preferably a polyurethane composition made with an aromatic polycarbonate intermediate, having a melting point that is, at a minimum, in excess of the melting point of the composition from which the intermediate component is formed (further discussed below).

There are many methods by which the inner component may be made, such as the many known methods used to produce porous compliant vascular prostheses. One such method is termed phase inversion or separation which involves dissolving a urethane in a solvent, such as dimethyl acetamide (DMA), forming a coat on a mandrel—such as by dipping the mandrel into the dissolved urethane—and then immersing the urethane coating in a solution such as water by which DMA may be dissolved, but not urethane, thereby causing the urethane to bead-up and form a porous matrix.

Another method by which the inner component may be formed is termed particle elution. The method utilizes water soluble particles such as salt (NaC1, MgC12, CaCo2, etc.) polymers, such as polyvinylpyrrolidone, sugars etc. The particles are mixed or blended into a urethane composition, and after forming a graft from the mixture such as by dip coating or extruding the particle filled plastic, the particle is eluted out with a suitable solvent.

Additional methods include replamineform, that involves the dissolution of a matrix, such as that of a sea urchin, out of the urethane with hydrochloric acid, spray techniques where filaments or beads of urethane are sprayed onto a mandrel to produce a porous vascular graft, and electrostatic deposition of urethane fibers from solution.

However, the porous vascular graft preferred in this invention is prepared according to the method detailed in U.S. Pat. No. 4,475,972 to Wong. This patent is incorporated hereinto by reference. An antioxidant may be added to further prevent degradation of the fibers drawn of the material from which the inner component is made.

Regardless of the nature and method of manufacturing the porous inner component, the intermediate component is comprised of one or more layers of a biocompatible synthetic material, preferably a polyurethane material, having a melting point lower than the melting point of the material from which the inner component is formed and lower than the melting point of the material from which the outer component is made.

The outer component comprises a mesh network made of strands, fibers, beads or expanded versions of a durable material such as a composition of fluorocarbons, such as expanded polytetrafluoroethylene ("ePTFE")—commonly termed Teflon—or stable polyesters, such as preferably polyethylene terephthalate ("PET")—commonly termed Dacron. This material is preferably warp-knitted in a tricot or double tricot pattern and shaped in a tubular configuration. It can also be appreciated that the outer component can be woven, braided,

weft-knitted and the like with loose fibers, textured fibers and the like to provide increased compliance. With the three components in place, a composite graft according to the present invention is formed by heating the structure to a temperature at or above the melting point of the material from which the intermediate component is formed but below the melting temperature or temperatures of the material from which the outer component is formed and of the material from which the inner component is formed. In this temperature range, the intermediate component may melt without the melting of either the inner component and the outer component, thereby mechanically bonding the inner component to the outer component.

The multi-component system of the present invention provides a number of advantages over conventional grafts. The use of a durable material, such as PET or ePTFE, from which the outer component may be formed is advantageous because of the known strength that such material has in the body. Devices made from PET or ePTFE when implanted in the body are known to maintain their integrity for some three decades. Further advantageously, it has been found that a graft—made according to the present invention and in which PET is used to form the outer component —has a burst strength and a tensile strength that is some two times greater than that of a conventional graft. Such strength prevents the dilation of the vessel in response to, for example, an increase in blood flow and/or pressure, creep relaxation of the urethane, biodegradation of the urethane, plasticization of the urethane, etc. Decreases in the strength of PET that may occur after implantation due, for example, to the absorption of water after implantation, are minimal as Dacron has a low water absorption ability.

The use of a knitted pattern according to which the durable strands of the outer component may be configured is advantageous due to the increased compliance such a pattern provides. As stated above, a durable material such as PET is recognized as a strong yet not necessarily compliant material. However, by knitting the strands from which the outer component is formed into a network, a compliant reinforcing outer component is formed. The use of such a material from which to form the outer component in the three component system of the present invention advantageously provides a strengthened, yet compliant graft.

The winding of strands of synthetic material, such as polyurethane over a mandrel to form an inner component is further advantageous because of the resultant porosity of the component. While the intermediate component may be made porous, for example, by painting synthetic material over the inner component and utilizing the phase inversion method or the particle elution method to form a porous matrix, preferably the intermediate component is formed by winding strands of synthetic material, such as polyurethane over the inner component, to provide a highly porous network. Utilizing strands of PET configured in a knitted pattern to form the outer reinforcement component further provides a porous network. Advantageously, by combining these individually porous components together in a composite graft, a totally porous integral graft results. Porosity is an advantage in medical devices, such as vascular grafts, because an open structure allows vascular fluid to infiltrate and communicate to and from the surrounding tissue and the interior of the graft and allows the ingrowth of tissue to occur within the graft. Accordingly, the device becomes better incorporated into the surrounding tissue, thereby further securing the device within the implantation site.

Uniting the three components into a single composite graft advantageously facilitates the use of the device. The graft may be implanted without the need for any assembly immediately prior to use. The graft may be also cut and/or sutured as a unit without the need for the separate cutting and/or suturing of each component. Methods for cutting the composite graft include scalpel, scissors, hot wires, shaped blades, and the like. The speed with which the graft may be implanted is a particularly distinct advantage since the device is implanted only when a patient is undergoing surgery.

The use of a polycarbonate intermediate rather than, for example, a polyether urethane to make the polyurethane material from which the inner component is preferably made is advantageous as the resultant inner component better resists degradation. The resistance to degradation is further aided by the addition of antioxidant to the material from which the inner component is formed.

It is, accordingly, a general object of the present invention to provide an improved graft.

Another object of the present invention is to provide an integral improved graft made from a composite of layers of synthetic materials.

It is also an object of the present invention to provide a graft that is totally porous thereby facilitating the incorporation of the graft into the site of implantation.

An additional object of the present invention is to provide an improved graft having an outer component which strengthens the device without significantly impairing the overall compliance of the graft.

These and other objects, features and advantages of this invention will be clearly understood and explained with reference to the accompanying drawings and through a consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

In the course of this description, reference will be made to the attached drawings, wherein:

FIG. 1 is a perspective view illustrating an embodiment of a composite vascular graft according to the present invention with an outer component of knitted durable material positioned over and bound by an intermediate component to an inner component; and

FIG. 2 is a cross sectional view of the composite vascular graft according to the present invention illustrated in FIG. 1.

DESCRIPTION OF THE PARTICULAR EMBODIMENTS

The present invention is a composite vascular graft—generally designated as 21 in FIGS. 1 and 2—comprised of an inner component 31, an intermediate component 41, and an outer component 61. The inner component will be described first.

Inner component 31 is fabricated from a biocompatible synthetic material, preferably polyurethane, having a melting temperature that is, at a minimum, greater than the melting temperature of the material from which the intermediate component is formed. Preferably, in those embodiments in which the inner component 31 is formed from polyurethane, it is made with an aromatic polycarbonate urethane. Polycarbonate urethanes are preferred over polyether urethanes due to

their superior biostability. The aromatic polycarbonate urethanes have melting points in the range of 150° C. to 230° C. This is in contrast to some aliphatic polycarbonate urethanes that have melting points between 90° C. and 130° C. It can also be appreciated that the inner member may be composed of non-urethane materials such as silicone rubber, polyolefins, fluoroelastomers, ePTFE, and the like. An antioxidant, such as Irganox 1010, may be added to the inner member to further prevent degradation of the strands from which the inner component is formed. The melting temperature of the material from which the inner component is preferably formed exceeds 150° C.

The methods by which the inner component 31 may be fabricated include those disclosed in U.S. Pat. No. 4,475,972 to Wong. According to a fabrication method taught in the Wong patent, termed "solution processing", the inner component material is dissolved in a solvent and forced out of one or more orifices to form one or more continuous fibers. The fibers are drawn directly onto a rotating mandrel. As the distributor or spinnerette reciprocates along the mandrel, non-woven strands are layered on top of each other to form porous, non-woven network of criss-crossing strands.

The intermediate layer 41 is formed of a biocompatible synthetic material, such as a polyolefin, a silicone thermoplastic material, etc., or preferably a polyurethane material having a melting temperature less than that of the materials from which the inner and outer components are formed. The intermediate layer can be drawn in the manner described in the Wong patent so that at least one fibrous layer is laid over the inner component 31 to form a porous intermediate layer. This intermediate layer can be spun from solution as described in the Wong patent or can be simply wound onto the inner layer from a spool of the biocompatible low melting point material. Alternatively, phase inversion or particle elution methods may be used to form a porous intermediate component. Examples of suitable low melting point biocompatible materials include the aliphatic polycarbonate or polyether urethanes with melting points of 90° C. to 130° C. The resultant porous, non-woven network of strands forming the intermediate component 41, as drawn over the inner component 31 form a unit 51 which facilitates the transmission of fluid.

Mesh 61, composed of strands of durable material, such as PET or ePFTE , knitted or woven in a generally elongated cylindrical shape and whose inner surface 63 is of a diameter equal to or slightly larger than the diameter of the outer surface 45 of the intermediate component 41, is fitted over the intermediate component 41. To provide compliance to the mesh network of strands from which the outer component is formed, the strands are configured preferably in a knitted pattern. Tricot or double tricot warp knit patterns are preferred. Double tricot patterns are further advantageous because they provide greater depth to the outer component 61 and thereby facilitate the acceptance of and retention of sutures and tissue ingrowth through the graft 21. Tricot or double tricot warp patterns are further advantageous in that they are generally more interlocking than other patterns and therefore resist "running". Other acceptable patterns according to which the strands of the outer component 61 may be formed include jersey or double jersey patterns, woven or braided and multiple layers of the above. Also, the fibers comprising the outer structure may be textured or non-textured and be of a variety of deniers.

The outer component 61 as positioned over the inner component and intermediate component is heated to a temperature equal to or greater than the temperature at which the material from which the intermediate component 41 is formed melts but less than the temperature and/or temperatures at which the material or materials from which the outer component and from which the inner component 31 is formed melts. When the inner component 31 is formed from the preferred material described above, the components are heated to a temperature less than 150° C. but greater than the temperature at which the material from which the intermediate component 41 is formed melts, such as 110° C. By maintaining the three components at such a temperature for a period of time, such as ten minutes, the intermediate component melts thereby securing the outer component 61 and the inner component 31 to each other. To further ensure the secure full engagement of the outer component 61 by the melted intermediate component 41, the outer component 61 may be forcefully pressed into the intermediate component 41 during the heating step such as mechanically and/or with or under pressure. After heating, the united three components are cooled thereby providing an integral mesh composite graft 21.

A mesh composite graft 21 according to the present invention is totally porous and compliant, yet advantageously includes a load bearing component, the outer component 61, which adds strength to the graft and prevents the failure of the graft even in response to greater fluid volume pressures from within, creep relaxation of the inner member and possible biodegradation effects of the inner member.

The advantageous compliance of the composite graft may be adjusted by varying the number of strands from which the inner component and the intermediate component 41 are formed. The compliance of the composite graft 21 may be adjusted also by varying the materials from which the inner component 31 and the intermediate component 41 are formed while maintaining the relationship that the intermediate component 41 must melt at a lower temperature than the materials from which the outer component and the material from which inner component 31 is formed. The compliance of the mesh composite graft 21 may be adjusted further by adjusting the angle at which the strands of the inner component 31 and/or the strands of the outer component 61 are laid down—a higher angle provides a less compliant component and thereby a less compliant graft.

The compliance may be adjusted even further by altering the knitting parameters, such as courses and wales per inch, the stitch density, the fiber denier, the number of strands per filament, the composition of the fibers and filaments such as a mixture of PET and Spandex compositions and whether the outer member is knitted, woven or braided.

The advantageous overall porosity of the graft 21 may be adjusted also in a number of ways. In addition to varying the size and number of the strands from which the inner component 31 and intermediate component 41 are formed, the strands of each component may be drawn at different angles to provide decreased pore size and resultant decreased porosity. Similarly, the porosity of the outer component 61, and thereby the porosity of the composite graft 21 may be varied by varying the

size and/or number of the strands and stitch density used to make the outer component mesh.

It can also be appreciated that the outer component need not be a tube formed specifically for this purpose from materials as above but can also be made from a vascular graft preformed from a porous matrix material such as ePTFE. One such graft is manufactured by W. L. Gore and marketed as a Gore-Tex graft. The ePTFE graft may be sheathed over the previously described inner and intermediate components and heat fused into a similar composite graft described in this document. Similarly, the inner members may be a Gore-Tex graft, the intermediate component, a heat fusable thermoplastic, and the outer component, a Dacron knit.

Regardless of the configuration of the inner, intermediate and outer components of the graft, i.e. be it spun, salt eluted, phase inverted, wound with an outer PET mesh, or in which an ePTFE configuration is utilized, the resultant composite graft 21 as formed may be implanted in vascular locations and retained in place through conventional methods, such as suturing. The preferred use of PET, knitted in a preferred tricot or double tricot pattern, from which to make the outer component 61 of the graft 21 provides a graft having a greater thickness than grafts without such a load bearing component. The outer component 61 facilitates the greater retention of the sutures within the graft.

It will be understood that the embodiments of the present invention as described are illustrative of some of the applications of the principles of the present invention. Modifications may be made by those skilled in the art without departure from the spirit and scope of the invention.

We claim:

1. A composite graft for implantation within a host, comprising:

an inner component made from wound, criss-crossing layers of fibers of a first biocompatible synthetic material and shaped to form a porous generally elongated cylindrical shape having a lumen through which blood may flow, said inner component having an outer surface;

an intermediate compliant bonding component made from wound, criss-crossing layers of fiber of a second biocompatible synthetic material, said second material having a melting point lower than the melting point of said first material and lower than the melting point of polyethylene terephthalate, said intermediate component positioned generally over and substantially covering said outer surface of said inner component, said intermediate component being porous and having an outer surface;

said intermediate component as positioned over said outer surface of the inner component forming a fluid transmission unit;

an outer component made from a mesh formed from strands of matrices of durable material, said strands or matrices preformed in a generally elongated cylindrical shape having a lumen therethrough and a diameter which is approximately equal to the outside diameter of said intermediate component, said outer component is positioned over and substantially covering said outer surface of the intermediate component; wherein each said outer component and said inner component is bonded to said intermediate component when each of the components is heated to a temperature less than the melting temperature of said firs material and said durable material thereby securing said components to each other to form a totally porous mesh composition graft.

2. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is polyurethane

3. The mesh composite graft according to claim 2, wherein said polyurethane is made with a polycarbonate intermediate.

4. The mesh composite graft according to claim 2, wherein said polyurethane is made with an aromatic polycarbonate urethane.

5. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is silicone rubber.

6. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is a polyolefin.

7. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said inner component is made is a fluoroelastomer.

8. The mesh composite graft according to claim 3, wherein said polyurethane includes an antioxidant to prevent degradation of said inner component.

9. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is polyurethane.

10. The mesh composite graft according to claim 9, wherein said polyurethane is an aliphatic polycarbonate.

11. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is a polyolefin.

12. The mesh composite graft according to claim 1, wherein said biocompatible synthetic material from which said intermediate component is made is a silicon thermoplastic material.

13. The mesh composite graft according to claim 1, wherein said outer component is further secured to said fluid transmission unit by pressing said outer component into said intermediate component during heating.

14. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate.

15. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate in a tricot pattern.

16. The mesh composite graft according to claim 1, wherein said mesh is formed by knitting said strands of polyethylene terephthalate in a double tricot pattern.

17. The mesh composite graft according to claim 2, wherein said mesh is formed from strands of expanded polytetrafluoroethylene.

18. The mesh composite graft according to claim 2, wherein said mesh is preformed from strands of polytetrafluoroethylene.

19. The mesh composite graft according to claim 2, wherein said mesh is a preformed porous matrix of expanded polytetrafluoroethylene.

* * * * *

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

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Matthew S. Goodwin
Name of applicant, assignee, or Registered Representative

(Signature)

DEC 10 1992

GROUP 1500

December 2, 1992
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

Please reconsider the above-identified application in view of the following remarks. These remarks are subdivided into a discussion of the claimed invention, and an analysis of the rejection, to facilitate an understanding of the significant differences between the cited art and the claimed invention.

Discussion of the Invention

A proper understanding of the invention is critical for appreciating the dissimilarities between the invention and the teachings of the cited references.

In a broad sense, the invention is a braided suture which contains dissimilar filaments of first and second fiber-forming materials. However, the proper characterization of the claimed suture goes far beyond this simple description.

The braided suture is made up of multifilament yarns. A multifilament yarn is a bundle of individual filaments which are integrated to form a single unit, that is, an individual multifilament yarn. The braided suture has a first and second set of these multifilament yarns in a braided construction. Each of the filaments of the first set of yarns is composed of a first fiber-forming material. Similarly, each of the filaments of the second set of yarns is composed of a second fiber-forming material.

The importance of the construction of the first and second set of yarns cannot be diminished. The braided construction is not accurately characterized by simply referring to a suture with filaments of dissimilar fiber-forming materials in a braided construction. Rather, filaments of a first fiber-forming material must be bundled to prepare a first set of multifilament yarns, and filaments of the second fiber-forming material must also be bundled to prepared the second set of multifilament yarns.

Once an understanding of the composition and construction of each set of first and second yarns is achieved, the importance of a further characterization of the braid construction can now be understood and appreciated. One yarn from the first set of yarns is in direct intertwining contact with a yarn from the second set of yarns. This limitation does not simply mean that the dissimilar filaments are fabricated into a braided construction, that is, dissimilar filaments are in "intertwining contact". Rather it is a multifilament yarn which is in direct intertwining contact with another multifilament yarn. Again, it is important to emphasize here that the multifilament yarns are integrated bundles of individual filaments, and it is this integrated bundle of filaments of a first fiber-forming material which is in direct intertwining

contact with another integrated bundle of individual filaments of a second fiber-forming material.

One way to accurately characterize the braided suture of this invention is to refer to it as a structured mechanical blend of dissimilar fiber-forming materials. The fiber-forming materials are first arranged into integrated bundles to form multifilament yarns and then these multifilaments yarns are further arranged so that at least one yarn from the first set of yarns directly intertwines with a multifilament yarn from the second set of yarns. This can be contrasted with a random, braided construction where filaments of dissimilar fiber-forming materials are randomly braided with one another to form a braided suture.

The heterogeneous braids of this invention exhibit truly outstanding and surprising properties. The integrity of the braid and therefore its properties is due entirely to the mechanical interlocking or weaving of the individual multifilament yarns (see the specification at page 4, lines 30-33). In the preferred embodiment, each yarn from the first set of multifilament yarns is in direct intertwining contact with a yarn of the second set to achieve the maximum degree of mechanical blending of the dissimilar multifilament yarns (see the specification at page 6, lines 28-31, and claim 15). In this way, yarn compatibility can be further enhanced and the overall physical and biological properties of the heterogeneous braid can be further improved as well.

What is truly surprising with respect to the claimed heterogeneous braid construction is that certain bulk properties of the claimed braid are better than what one skilled in the art would expect. A skilled artisan would expect the properties of the braid to simply follow the "Rule of Mixtures", where the bulk property

measured would be estimated to be a weighted average of its component properties. Upon studying the Examples in the specification, it will be noted that the bending rigidity of the heterogeneous braids in Examples 1 and 2 do not follow the Rule of Mixtures, but surprisingly show an enhanced bending rigidity relative to the weighted average of their filament components. This behavior is not achieved when dissimilar individual filaments are randomly braided to form the braided suture.

In setting forth the claimed invention, the heterogeneous braid does not encompass braided sutures with randomly braided individual filaments, as described in detail above. Further, the claimed heterogeneous braid could not be construed to cover known braids which have a core of longitudinally extending yarns composed of filaments of a first fiber-forming material, and a sheath of braided yarns composed of a second set of filaments of a dissimilar fiber-forming material. This braid construction does not fall within the scope of the claimed braid because these sheath yarns are not in direct intertwining contact with any of the core yarns. In other words, none of the sheath yarns are braided about a core yarn, but simply shroud the core yarns to form the sheath construction.

Analysis of the Rejection

1. Claims 21 and 23 were rejected under 35 USC §102(b) as being clearly anticipated by Doddi et al. ("Doddi"). Doddi does not anticipate the claimed suture, and therefore this rejection should be withdrawn.

The Examiner has correctly pointed out that Doddi does indeed disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56).

However, as discussed in detail above, more is required to meet the limitations of the claimed suture than just a disclosure concerning filaments of two different polymers in a braided configuration. Doddi teaches nothing more than braiding individual filaments, and fails to provide any guidance as to how that braiding should be carried out. Therefore, one skilled in the art would be lead to believe that what Doddi had in mind was to simply braid individual filaments in a randomized fashion to fabricate a multifilament suture. It is important enough, however, to reemphasize again that the claimed braid requires the bundling of individual filaments into an integrated unit to form a multifilament yarn. It is this multifilament yarn which directly intertwines with another multifilament yarn to form Applicants' braid construction.

Since Doddi only teaches randomly braiding filaments of dissimilar fiber-forming materials, it does not anticipate the claimed braided suture. Doddi simply fails to enable one skilled in the art to construct a braided suture in the manner set forth by Applicants, and it is axiomatic that a reference which lacks enablement is deficient as a reference to anticipate a claimed invention. Accordingly, it is respectfully requested that the rejection of claims 21 and 23 under 35 USC §102(b) as being clearly anticipated by Doddi be withdrawn.

2. Claims 22 and 24 were rejected under 35 USC §103 as being unpatentable over Kaplan et al. ("Kaplan") taken with Doddi. The Examiner asserts it would have been obvious to substitute PET and PTFE fibers of Doddi for the filaments of Kaplan to arrive at Applicants' claimed suture. Applicants respectfully traverse this rejection for the reasons given below.

The Examiner correctly points out that Kaplan discloses a ligament prosthesis made from a core component and a braided sheath component as illustrated in Figures 3 and 4, and discussed at column 8, line 65, through column 9, line 34. However, Kaplan suffers from the same deficiencies as does Doddi, and therefore fails to teach or suggest the claimed braided suture.

Firstly, the Examiner has made specific reference to the Kaplan specification regarding the makeup of the core components and the sheath yarn component. The only component which has a braided construction is the sheath yarn component. It is clear from Figure 3 of Kaplan that none of the sheath yarn components are in direct intertwining contact with the core component. In other words, the sheath yarn component is a true "sheath" which shrouds the core but is not in any way integrally braided with the core. Therefore, since the core is not in a braided construction, its composition is irrelevant with respect to the claimed braided suture.

When the focus is shifted to the more relevant aspect of the Kaplan disclosure, specifically the sheath yarn component, the Examiner has correctly pointed out that the sheath yarn component may be "fabricated from individual filaments having more than two different chemical compositions, one or more of which optionally being non-absorbable". (Column 9, lines 25-28). However, Kaplan neither teaches nor suggests how his sheath yarn component is to be fabricated from these dissimilar individual filaments, nor is there any guidance to one skilled in the art as to how such dissimilar individual filaments are to be braided. Accordingly, just as was the case with the deficient Doddi reference, one skilled in the art could only be lead to randomly braid the dissimilar individual filaments into a braid construction.

The teaching of Kaplan once again lacks the essence of the claimed invention, which is: bundled filaments of a first fiber-forming material form a first set of a multifilament yarns, and at least one of these multifilament yarns is intertwined with a multifilament yarn composed of bundled filaments of a second fiber-forming material. To put it bluntly, Kaplan teaches randomized braiding, and the claimed suture sets forth a structured braid. This difference is not trivial, as pointed out with reference to the discussion of Applicant's specification, and particularly Examples 1 and 2.

It should also be pointed out here that even if Doddi and Kaplan were combined, their combined teachings would still fail to meet the limitations of the claimed braided suture. This is so because neither reference, taken singularly or in combination, discloses a structured braid set forth in the claims, but merely sets forth randomized braiding of individual filaments.

For all of the reasons given above, especially taken in light of the detailed discussion of the claimed braided suture and its surprising advantages, the rejection of claims 22 and 24 under 35 USC §103 as being unpatentable over Kaplan taken with Doddi is improper. Accordingly, it is respectfully requested that this rejection be withdrawn.

3. Applicants acknowledge with gratitude the withdrawal of the rejection of claims 21-24 under 35 USC §103 as being unpatentable over Burgess, expressed in the previous Office Action dated July 8, 1992. (Paper No. 3). It is presumed that Applicants' response to this rejection in their Amendment dated August 6, 1992, spelling out the distinctions between Burgess and the claimed

invention, clearly convinced the Examiner that the claimed surgical suture is patentable over this art.

4. The prior art made of record and not relied upon by the Examiner is duly noted, and does not affect the patentability of Applicants' claimed invention.

5. Since all formal requirements appear to have been met, and the claimed invention is patentable over the art of record or any other art of which Applicants are aware, Applicants respectfully solicit a Notice of Allowance at the Examiner's earliest convenience.

Respectfully submitted,

Matthew S. Goodwin
Attorney for Applicant
Reg. No. 32,839

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2794
December 2, 1992

Case Docket No.: ETH-782

In re application of Alastair W. Hunter et al.

Serial No. 838,511

Filed 21 February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

[ ] No additional fee is enclosed because this application was filed prior to October 25, 1965 (effective date of Public Law 89-83).

[X] No additional fee is required.

[X] One stamped, self-addressed postcard for the PTO Mail Room date stamp.

[ ] Petition For Extension of Time and charge to Deposit Account of Appropriate Fee.

The fee has been calculated as shown below.

CLAIMS AS AMENDED

(1)	(2)	(3)	(4)	(5)	(6)	(7)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
TOTAL CLAIMS	* 24	minus	** 24	= 0	x $22	= $ 000.00
INDEP. CLAIMS	* 1	minus	*** 3	= 0	x $74	= $ 000.00
			TOTAL ADDITIONAL FEE FOR THIS AMENDMENT			$ 000.00

* If the entry in Col.2 is less than the entry in Col.4, write "0" in Col.5
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

[X] Charge $ 000.00 to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

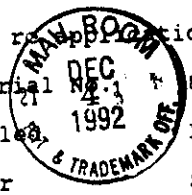
[X] Please charge any additional fees in connection with the filing of this communication, or credit overpayment, to Deposit Account No. 10-750/ETH-782/MSG. Three copies of this sheet are enclosed.

[ ] A check in the amount of $ _____ is attached.

Matthew S. Goodwin
Attorney of Record
Reg. No. 32,019

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
December 2, 1992

Case Docket No.: ETH-782

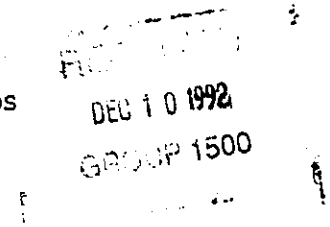


In re application of Alastair W. Hunter et al.

Serial No.: 07/838,511

Filed: February 19, 1992

For: STERILIZED HETEROGENEOUS BRAIDS



THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

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[ ] A check in the amount of $ _____ is attached.

Attorney of Record
Reg. No. 32,019

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
December 2, 1992

Case Docket No.: 5 ETH-782

In re application of Alastair W. Hunter et al.

Serial No. 838,511

Filed February 19, 1992

For STERILIZED HETEROGENEOUS BRAIDS

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

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CLAIMS AS AMENDED

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Attorney of Record
Reg. No. 32,019

Matthew S. Goodwin
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933-7003
(908) 524-2791
December 2, 1992

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/838,511	02/19/92	HUNTER A	ETH-782

EXAMINER	
RAYMOND, C	
ART UNIT	PAPER NUMBER
1504	7

15N1

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

DATE MAILED: 03/18/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☑ Responsive to communication filed on Dec. 2, 1992 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 24 are pending in the application.
   Of the above, claims 1 - 20 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 21 - 24 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000246

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 21 is rejected under 35 U.S.C. § 102(e) as being anticipated by Kaplan et al.

Kaplan et al. discloses a connective tissue prosthesis comprising a braided sheath yarn component and a core yarn component. The braided sheath comprises braided filaments or braided filament bundles (column 9, lines 4-12). A sheath component containing filaments of different chemical compositions is specifically disclosed (column 9, lines 12-16). Claim 21 is therefore anticipated by Kaplan et al.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as

prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 21-24 are rejected under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al.

Doddi et al. disclose a surgical suture comprising filaments of two different polymers in a braided configuration (column 9, lines 47-56). Suitable biocompatible, non absorbable filaments include PET and PTFE (column 9, lines 51-53).

Kaplan et al. discloses a ligament prosthesis comprising a core component and a braided sheath component. The core component is "made up of one or more biocompatible, essentially non-bioabsorbable..." filaments (column 9, lines 1-3). The sheath yarn component may be fabricated from one or more non-bioabsorbable fibers (column 9, lines 25-28). It would have been obvious to form the sheath component of the device of Kaplan et al. from PTFE and PET. PTFE is known to inpart improved knot run down properties to sutures (see Block U.S. Pat. No. 3,527,650). PET is noted for its low cost and high strength. The core yarn component must be non-bioabsorbable (column 4, lines 45-46). Since PET is non-bioabsorbable, biocompatible and has the desirable properties noted above, its use as the core component would have been obvious. Claims 21 and 22 are therefore unpatentable over Doddi et al. taken

with Kaplan et al.

Kaplan et al. fail to disclose the prosthesis of their invention connected to a needle. Prosthesis are, however, implanted in the body using a needle. Claims 23 and 24 are therefore unpatentable over Doddi et al. taken with Kaplan et al.

Applicant's arguments with respect to claims 21-24 have been considered but are deemed to be moot in view of the new grounds of rejection.

Any inquiry concerning this communication should be directed to Chris Raimund at telephone number (703) 308-2374.

C. Raimund:pdw
February 25, 1993

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

August 4, 1993
(Date of Deposit)

Hal Brent Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Submitted herewith on Form PTO-1449, is a listing of documents known to the Applicants and/or their attorney in compliance with the requirements of 37 C.F.R. §1.56. Copies of these documents are also being submitted.

These documents are being submitted after the first Office Action. Accordingly, the Patent and Trademark Office is authorized to charge Account No. 10-750/ETH-782/HBW the appropriate fee under 37 C.F.R. §1.17(p) for the citation of these documents. Three copies of this statment are included.

CS14107 09/08/93 07838511 10-0750 140 126 200.00CH

Consideration of the cited documents and making the same of record in the prosecution of the above-noted application are respectfully requested.

Respectfully submitted,

Hal B. Woodrow
Reg. No. 32,501

JOHNSON & JOHNSON
One Johnson and Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

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Hal Brent Woodrow
(Signature)

August 3 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

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Consideration of the cited documents and making the same of record in the prosecution of the above-noted application are respectfully requested.

Respectfully submitted,

Hal B. Woodrow
Reg. No. 32,501

JOHNSON & JOHNSON
One Johnson and Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976

Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

Docket No.	Serial No
ETH-782	838,511
Applicant: Alastair W. Hunter, et al.	
Filing Date: Feb. 19, 1992	Group Art Unit: 1504

U.S. PATENT DOCUMENTS

Exam'r Init.	Document No.	Date	Name	Class	Sub Class	File Date
CWR	3,463,158	8/26/69	Edward Emil Schmitt, et al.	606	228	1/9/67
CWR	4,979,956	12/25/90	Thomas A. Silvestrini	623	13	7/10/89
CWR	3,636,956	1/25/72	Allan K. Schneider	128	335.5	5/13/70
CWR	4,141,087	2/27/79	Shalaby W. Shalaby, et al.	3	1	1/19/77
CWR	4,959,069	9/25/90	Karl W. Brennan, et al.	606	228	10/20/89

FOREIGN PATENT DOCUMENTS

Exam'r Init.	Document No.	Date	Country	Class	Sub Class	Translate Yes	Translate No
CWR	GB 2 082 213	8/16/80	Great Britian	—	—	✓	

OTHER REFERENCES (include author, title, date, pertinent pages, etc.)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000254

Examiner: [signature] Date Considered: NOVEMBER 8, 1993

Examiner: Initial if citation considered, whether or not citation is in confirmance with MPEP §609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

DOCKET NO. ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

ASSOCIATE POWER OF ATTORNEY

Sir:

In the matter of the above-identified application, I hereby appoint Hal Woodrow (Reg. No.32,501), whose postal address is One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003, my associate attorney to prosecute said application, to make alterations and amendments therein, to file continuing applications claiming the benefit of said application, to receive the patent and to transact all business in the Patent Office connected with said application.

I request all communications with respect to said application be addressed to Audley A. Ciamporcero, Jr., One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003. All telephone calls should be directed to Hal Woodrow at (908) 524-2976.

Signed at New Brunswick, in the County of Middlesex and State of New Jersey, this 3rd day of August, 1993.

Attorney for Applicant(s)
Jason Lipow Reg. No. 25509

One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATED: August 3, 1993

CKET NO. ETH-782 Cp154

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

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August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

August 3, 1993
(Date of Signature)

SEP 1 1993

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

PETITION FOR EXTENSION OF TIME
AND AUTHORIZATION TO CHARGE
DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicant(s) petition(s) the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated March 18, 1993 for two (2) month(s) from June 18, 1993 to August 18, 1993. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-750/ETH-782/HBW in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

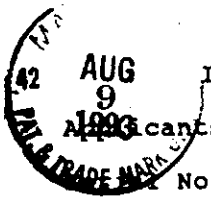
P 30003 08/30/93 07838511 10-0750 030 116 360.00CH

Respectfully submitted,

Hal Brent Woodrow

Hal B. Woodrow
Reg. No. 32051
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATE: August 4, 1993



DOCKET NO. ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Ser. No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

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Hal B. Woodrow
Name of applicant, assignee, or Registered Representative

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August 3, 1993
(Date of Signature)

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Washington, D.C. 20231

SEP 1 1993

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SEP 1 1993

Respectfully submitted,

Hal Brent Woodrow
Hal B. Woodrow
Reg. No. 32051
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
DATE: August 4, 1993

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

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August 4, 1993
(Date of Deposit)

Hal B. Woodrow
Name of Applicant, Assignee, or Registered Representative

(Signature)

August 3, 1993
(Date of Signature)

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

AMENDMENT

Dear Sir:

This amendment is responsive to the Office Action of March 18, 1993.

IN THE CLAIMS

Please amend claim 21 as follows:

(Once Amended)

~~21~~. A surgical suture [comprising] consisting essentially of a [the] heterogeneous braid [of claim 1] composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set; and

a) each yarn from the first set is composed of a plurality of filaments of a first fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE; and

b) each yarn from the second set is composed of a plurality of filaments of a second fiber-forming material selected from the group consisting of PET, nylon and aramid; and

c) optionally a core.

26

CLAIM 2

REMARKS

Please note that the attorney prosecuting this application for the assignee, Johnson & Johnson, is now Hal Brent Woodrow (Reg. No. 32,501). This change has been authorized by the Associated Power Attorney submitted herewith. No change in the address for correspondence is necessary.

Claim 21 has been amend to place this claim in proper form for allowance. Claim 21 as amended claims a heterogeneous braid composed of a first and second set of yarns. The first set of yarns are made of a fiber-forming material selected from the group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP, and PE materials. The second set of yarns are made of a fiber-forming material selected from the group consisting PET, nylon and aramid materials. Support for there amendments may be found in the specification on page 4, lines 12-22 and page 8, lines 3-23. Accordingly, applicants request entry of this amendment and reconsideration of claim 21.

The rejection of claim 21 under 35 U.S.C. §102(e) as being anticipated by Kaplan et al. has been reviewed. However, applicants respectfully submit that claim 21 as amended is not anticipated by Kaplan. Kaplan, as stated by the Examiner, describes a connective tissue prosthesis comprising a braided sheath yearn component and a core yarn component. The sheath yarn being a biocompatible yarn that is bioabsorbable or semi-bioabsorbable (column 9 lines 10-12). In one embodiment the sheath yarn could also contain a non-bioabsorbable yarn of one or more chemical composition (column 9 line 25-27). Claim 21 as amended does not claim a sheath yarn composed of a bioabsorbable yarn. Accordingly, Kaplan et al. does not anticipate claim 21 under 35 U.S.C. § 102(e). Therefore, applicants request reconsideration and withdrawal of the rejection of claim 21 as being anticipated by Kaplan et al.

Applicants have also reviewed the rejection of claims 21-24 under 35 U.S.C. § 103 as being unpatentable over Doddi et al. taken with Kaplan et al. However, applicants respectfully submit that claims 21-24 are patentable over these documents.

Doddi et al. describes (column 9, lines 46-56) multifilament sutures composed of p-dioxanone and/or 1,4 dioxepan-2-one and alkyl substituted derivatives that may be woven, braided or knitted, either alone or in combination with nonabsorbable fibers. Although Doddi is a significant contribution to the art, Doddi does not describe heterogeneous braids formed from a first set of yarn composed of a plurality of filaments formed from materials selected

from the group consisting of PTFE, FEP, PFA PVDF, PETFE, PP and PE; and a second set of yarn composed from a plurality of filaments formed from materials selected from the group consisting of PET, nylon and aramid. Accordingly, Doddi alone would not render the present invention obvious.

Kaplan et al. as discussed previously describes a prosthesis comprising a core component and a braided sheath component. The sheath component which is designed to "erode over time" (column 9, line 52) to leave only the nonabsorbable core component. The sheath, however, may optionally have, in addition to the bioabsorbable sheath yarn, one or more non-bioabsorbable filaments. Applicants, therefore, respectfully submit that Kaplan does not suggest or disclose combining a first set of nonabsorbable yarns (i.e. PTFE) and a second set of nonabsorbable yarn (i.e. PET). In fact, Kaplan teaches away from this combination.

In column 2, Kaplan describe one of the objects of their invention as being "a prosthesis being formed of a composite yarn wherein an elastic core yarn is wrapped with a relatively inelastic, bioabsorbable or semi-absorbable sheath yarn so as to exhibit the stress-strain properties of natural tissue" (column 2, lines 36-41). In column 4, Kaplan describes fluorinated hydrocarbons, polypropylene and polyethylene as elastic core polymers as opposed to the inelastic sheath polymers desired in the sheath. Thus, Kaplan appears to suggest that the sheath yarns listed by the applicant in claim 21 should not be used as in sheaths. Applicants respectfully submit that in view of Kaplan teaching away from the present invention that the combination of Kaplan with Doddi does not render the present invention obvious. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 21-24.

The citation of Block (U.S. Patent No. 3,527,650) has also been considered, but is respectfully submitted to be non-analogous art. Block describes the use of PTFE particles on the external surface of a PET suture as a lubricant. Block, however, does not suggest or disclose PTFE fiber as having a lubricating effect. Therefore, Block's use of PTFE particles does not suggest or disclose the use of PTFE fibers in braids.

Applicants also wish to alert the Examiner to the applicants' intent to change the inventorship because of the reduced scope of the claims. Dennis D. Jamiolkowski will no longer appear as an inventor if the present claims are allowed. Papers to effectuate this changed inventorship will be submitted when one or more of the present claims are indicated to be allowable.

Respectfully requested,

Hal Brent Woodrow

Hal B. Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
Date: August 31 1995

GP 1504

ETH-782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Alastair W. Hunter, et al.

Serial No.: 838,511 Art Unit: 1504

Filed : February 19, 1992 Examiner: C. Raimund

For : STERILIZED HETEROGENEOUS BRAIDS

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231 on

November 9, 1993
(Date of Deposit)
Hal Brent Woodrow
Name of applicant, assignee, or Registered Representative

Hal Brent Woodrow
(Signature)

November 9, 1993
(Date of Signature)

11-24-93
7560
Raimund

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

SUPPLEMENTAL AMENDMENT

Dear Sir:

This Supplemental Amendment is an amendment to the Amendment submitted on August 4, 1993.

REMARKS

Applicants have noticed that the Amendment of August 4, 1993 under the heading "In The Claims" states, "Please amend claim 2 as follows:", however, the claim designated as being amended is claim

Noted - corrected by Examiner -
M Lorner (SPE)
12-30-93

21. Applicants respectfully request this sentence be changed to read "Please amend claim 21 as follows:".

H. Brent Woodrow

Hal Brent Woodrow
Reg. No. 32,501
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
November 9, 1993

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/[illegible],513	[illegible]	HUNTER	[illegible]

15N1/11.3

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
ART UNIT	PAPER NUMBER
1[illegible]	1[illegible]

DATE MAILED: 11/[illegible]/93

NOTICE OF ALLOWABILITY

PART I.

1. ☑ This communication is responsive to the Amendment filed August 9, 1993.
2. ☑ All the claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
3. ☑ The allowed claims are 21, 23, 24, 7, 8, 10-12, 14, 18-20.
4. ☐ The drawings filed on _____ are acceptable.
5. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [_] been received. [_] not been received. [_] been filed in parent application Serial No. _____, filed on _____.
6. ☑ Note the attached Examiner's Amendment.
7. ☐ Note the attached Examiner Interview Summary Record, PTOL-413.
8. ☐ Note the attached Examiner's Statement of Reasons for Allowance.
9. ☐ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
10. ☑ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

1. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
2. ☐ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
   a. ☐ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No. _____. CORRECTION IS REQUIRED.
   b. ☐ The proposed drawing correction filed on _____ has been approved by the examiner. CORRECTION IS REQUIRED.
   c. ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
   d. ☐ Formal drawings are now REQUIRED.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

Attachments:

- ✓ Examiner's Amendment
- _ Examiner Interview Summary Record, PTOL-413
- _ Reasons for Allowance
- _ Notice of References Cited, PTO-892
- ✓ Information Disclosure Citation, PTO-1449
- _ Notice of Informal Application, PTO-152
- _ Notice re Patent Drawings, PTO-948
- _ Listing of Bonded Draftsmen
- _ Other

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000264

PTOL-37 (REV. 4-89) *

USCOMM-DC 69-5788

Part III EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Hal B. Woodrow on November 15, 1993.

Permission was given to amend the claims as follows:

Cancel claims 1 - 6, 9, 13, 15, 16, 17 and 22.

In claims 7, 8, 10, 11, 12, 14, 18, 19 and 20, line 1, change "heterogeneous braid" to "surgical suture".

In claim 7, line 1, change "6" to "21".

In claim 10, line 1, change "9" to "8".

In claim 14, line 1, change "13" to "12".

In claim 18, line 1, change "17" to "14".

In claim 20, line 1, change "1" to "21".

In claim 24, line 1, change "22" to "14".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Raimund whose telephone number is (703) 308-2374.

Chris Raimund/cwr
November 15, 1993

GEORGE F. LESMES
SUPERVISORY PATENT EXAMINER
GROUP 150

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: Box ISSUE FEE
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

15N1/111.

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

☐ Note attached communication from the Examiner
☐ This notice is issued in view of applicant's communication filed ____________

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT		DATE MAILED
07/938,511	09/19/92	012	RAYMOND, [illegible]	[illegible]	[illegible]

First Named Applicant: HUNTER, ALASTAIR W.

TITLE OF INVENTION: STERILIZED HETEROGENEOUS BRAIDS

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
[illegible]	ETH-730	606-231.000	S67	UTILITY	NO	[illegible]	[illegible]

THE FEE DUE IS THE AMOUNT IN EFFECT AT THIS TIME. IF THE AMOUNT OF THE ISSUE FEE INCREASES PRIOR TO PAYMENT, APPLICANT WILL BE NOTIFIED OF THE BALANCE OF ISSUE FEE DUE.

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.

PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY Status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

  A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
  B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:
A. Pay FEE DUE shown above, or
B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date) and serial number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (REV.7-92) (OMB Clearance is pending) PATENT AND TRADEMARK OFFICE COPY

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No. 04-12457 PBS
DMI000266

PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advances orders and notification of maintenance fees will be mailed to address entered in Block 1, unless you direct otherwise, by: (a) specifying a new correspondence address in Block below, or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. **See reverse for Certificate of Mailing.**

MAIL ROOM FEB 18 1994 PAT. & TRADEMARK OFF. 68

1 CORRESPONDENCE ADDRESS	2 INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)
JOHNSON PLAZA	INVENTOR'S NAME Street Address City, State and ZIP Code CO-INVENTOR'S NAME Street Address City, State and ZIP Code ☐ Check if additional changes are on reverse side

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED

First Named Applicant

TITLE OF INVENTION

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
		606-231.000	56	UTILITY	NO	1170.00	

3. Correspondence address change (Complete only if there is a change)

30431 02/22/94 07838511
P. 30432 02/22/94 07838511

10-0750
10-0750

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.

1 Hal Brent Woodrow
2
3
170.00CH
30.00CA

DO NOT USE THIS SPACE

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)

(1) NAME OF ASSIGNEE: Ethicon, Inc. Recorded- 2/19/92 Reel-6023 Frame-941

(2) ADDRESS: (CITY & STATE OR COUNTY) Somerville, N.J.

(3) STATE OF INCORPORATION, IF ASSIGNEE IS A CORPORATION: Ohio

A ☐ This application is NOT assigned.
☒ Assignment is being previously submitted to the Patent and Trademark Office.
☐ Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.

PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

6a. The following fees are enclosed:
☐ Issue Fee ☐ Advanced Order - # of Copies _____ (Minimum of 10)

6b. The following fees should be changed to:
DEPOSIT ACCOUNT NUMBER 10-0750
(ENCLOSED PART C)
☒ Issue Fee ☒ Advanced Order - # of Copies 10 (Minimum of 10)
☐ Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Signature of party in interest of record)	(Date)
32,501 Hal Brent Woodrow	2/16/94

NOTE: This Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

TRANSMIT THIS FORM WITH FEE-CERTIFICATE OF MAILING ON REVERSE

PTOL-85B (REV.7-92)(OMB Clearance is pending)

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Box ISSUE FEE
Commissioner of Patents and Trademarks
Washington, D.C. 20231

94 FEB 18 PM 8:55
PATENT & TRADEMARK OFC
IRSB DIVISION

on February 16, 1994
(Date)

Hal Brent Woodrow
(Signature)

Hal Brent Woodrow
(Typed or Printed Name)

February 16, 1994
(Date)

Note: If this certificate of mailing is used, it can only be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

This form is estimated to take 20 minutes to Complete. Time will vary depending upon the needs of the individual applicant. Any comments on the amount of time you require to complete this form should be sent to the Office of Management and Organization, Patent and Trademark Office, Washington, D.C. 20231 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

PART B—ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advances orders and notification of maintenance fees will be mailed to addressee entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block below; or (b) providing the PTO with a separate "FEE ADDRESS" for maintenance fee notifications with the payment of Issue Fee or thereafter. **See reverse for Certificate of Mailing.**

MAIL ROOM FEB 18 1994 PATENT & TRADEMARK OFF.

1. CORRESPONDENCE ADDRESS	2. INVENTOR(S) ADDRESS CHANGE (Complete only if there is a change)
	INVENTOR'S NAME
	Street Address
	City, State and ZIP Code
	CO-INVENTOR'S NAME
	Street Address
	City, State and ZIP Code
	☐ Check if additional changes are on reverse side

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED

First Named Applicant

TITLE OF INVENTION

2/18/94

	ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
	ETH-732			UTILITY	NO	$1170.00	02/18/94

3. Correspondence address change (Complete only if there is a change)

4. For printing on the patent front page, list the names of not more than 3 registered patent attorneys or agents OR alternatively, the name of a firm having as a member a registered attorney or agent. If no name is listed, no name will be printed.

1 Hal Brent Woodrow

2

3

DO NOT USE THIS SPACE

5. ASSIGNMENT DATA TO BE PRINTED ON THE PATENT (print or type)

(1) NAME OF ASSIGNEE: Ethicon, Inc. Recorded: 2/19/92 Reel-6023 Frame-941

(2) ADDRESS: (CITY & STATE OR COUNTY) Somerville, N.J.

(3) STATE OF INCORPORATION, IF ASSIGNEE IS A CORPORATION: Ohio

A. ☐ This application is NOT assigned.
☒ Assignment is being previously submitted to the Patent and Trademark Office.
☐ Assignment is being submitted under separate cover. Assignments should be directed to Box ASSIGNMENTS.
PLEASE NOTE: Unless an assignee is identified in Block 5, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the PTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

6a. The following fees are enclosed:
☐ Issue Fee ☐ Advanced Order - # of Copies: (Minimum of 10)

6b. The following fees should be changed to:
DEPOSIT ACCOUNT NUMBER 10-0750
(ENCLOSED PART C)
XXIssue Fee XXAdvanced Order - # of Copies 10 (Minimum of 10)
☐ Any Deficiencies in Enclosed Fees

The COMMISSIONER OF PATENTS AND TRADEMARKS is requested to apply the Issue Fee to the application identified above.

(Signature of party in interest of record) 32,501 Hal Brent Woodrow (Date) 2/16/94

NOTE: If the Issue Fee will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the Patent and Trademark Office.

TRANSMIT THIS FORM WITH FEE-CERTIFICATE OF MAILING ON REVERSE

PTOL-85B (REV.7-92)(OMB Clearance is pending)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000269

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Box ISSUE FEE
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Washington, D.C. 20231

on February 16, 1994
(Date)

Hal Brent Woodrow
(Signature)

Hal Brent Woodrow
(Typed or Printed Name)

February 16, 1994
(Date)

Note: If this certificate of mailing is used, it can only be used to transmit the Issue Fee. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing.

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000270

This form is estimated to take 20 minutes to Complete. Time will vary depending upon the needs of the individual applicant. Any comments on the amount of time you require to complete this form should be sent to the Office of Management and Organization, Patent and Trademark Office, Washington, D.C. 20231 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

REVERSE FTOL-858 (REV. 7-92)(OMB Clearance is pending)

1504

ETH 782

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Alastair W. Hunter, Dennis D. Jamiolkowski and Arthur Taylor, Jr.

Serial No. 07/838,511 Group No. 1504

Filed: February 19, 1992 Examiner: C. Raimund

For: STERILIZED HETEROGENOUS BRAIDS

CERTIFICATE OF MAILING (37 CFR 1.8(a))

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Hal Brent Woodrow
Name of Person Mailing Paper

Date: November 22, 1993 Hal Brent Woodrow
Signature of Person Mailing Paper

12-6-93

Commissioner of Patents and Trademarks
Washington, D. C. 20231

7560
Raimund

AMENDMENT, PETITION AND FEE DELETING CORRECTLY NAMED ORIGINAL PERSON(S) WHO ARE NOT INVENTOR(S) OF INVENTION NOW BEING CLAIMED (37 CFR 1.48(b)

1. This amendment and petition under 37 CFR 1.48(b) is to delete the name(s) of the following person(s) originally named as inventor(s) of the invention now being claimed:

Dennis D. Jamiolkowski

2. Claims Now On File

The claims in this application are as follows:

OK to enter
MH

[ ] originally filed claim(s) _____

[ ] originally filed claims _____ as amended on _____

[ ] claim(s) _____ filed on _____

[X] claim(s) 21-24 filed on February 19, 1992 as amended on August 4, 1993 and amended by the Examiner's Amendment of November 15, 1993

P 30079 12/07/93 07838511 10-0750

[X] claims 25-33 added by the Examiner's Amendment of November 15, 1993

3. **DILIGENCE**

This amendment and petition is being filed

[X] diligently after discovery that any claim(s) for which the above-named inventor who is being deleted are now no longer the inventor of the subject matter being claimed.

4. **STATUS OF INVENTORSHIP AFTER AMENDMENT**

[ ] Attached is an explanation of the facts, including the ownership of all the claim(s) at the time the last claimed invention was made (Declaration of Inventorship and Common Ownership of Claims in Application).

5. **FEE (37 CFR 1.17(h)**

The fee required is paid as follow:

[X] charge Account No. 10-750/HBW/ETH-782 for any fee deficiency

[X] charge Account No. 10-750/HBW/ETH-782 the sum of $130.00

Hal Brent Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(908) 524-2976
November 22, 1993

PTO UTILITY GRANT
Paper Number 14

The United States of America

The Commissioner of Patents and Trademarks

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person or persons having title to this patent the right to exclude others from making, using or selling the invention throughout the United States of America for the term of seventeen years from the date of this patent, subject to the payment of maintenance fees as provided by law.

Bruce Lehman

Commissioner of Patents and Trademarks

Sandra L. Morton

Attest

PTO-1584

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000273

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/838,911	02/19/92	HUNTER	[illegible]

15N1/0527

ROBERT L. MINIER
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

ART UNIT	PAPER NUMBER
1504	

DATE MAILED 05/27/94

A. ☐ The petition filed _____ under 37 CFR 1.312(b) is granted.
The paper has been forwarded to the examiner for consideration on the merits.

B. ☒ The amendment filed 2/16/94 under 37 CFR 1.312 has been considered, and has been:

1. ☐ entered
2. ☒ entered as directed to matters of form not affecting the scope of the invention (0.3311).
3. ☐ disapproved. A report appears below.
4. ☐ entered in part. A report appears below.

Report:

SUPERVISORY PATENT EXAMINER
GROUP 150

PLEASE FURNISH YOUR ZIP CODE IN ALL CORRESPONDENCE

FORM PTOL-271 (REV. 7/89)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000274

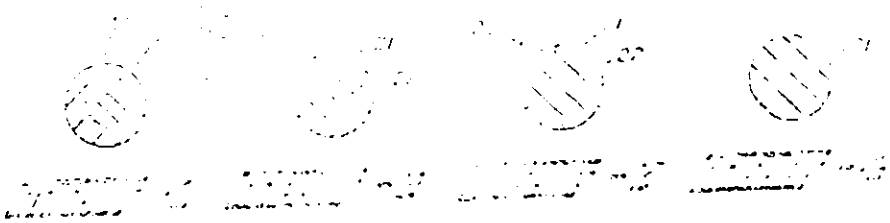
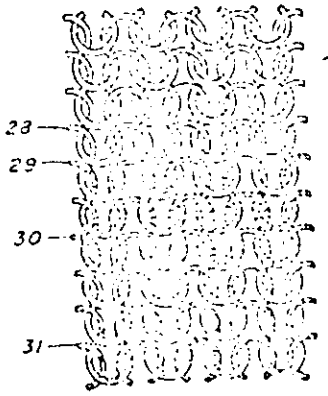


FIG - 5 FIG - 6 FIG - 7



- 100% NON-ABSORBABLE
- 75% NON-ABSORBABLE - 25% PGA
- 50% NON-ABSORBABLE - 50% PGA
- 25% NON-ABSORBABLE - 75% PGA

FIG - 8

INVENTORS.
EDWARD EMIL SCHMITT
ROCCO [illegible]LBERT POLISTINA
BY
Samuel Brooks Fiske
ATTORNEY

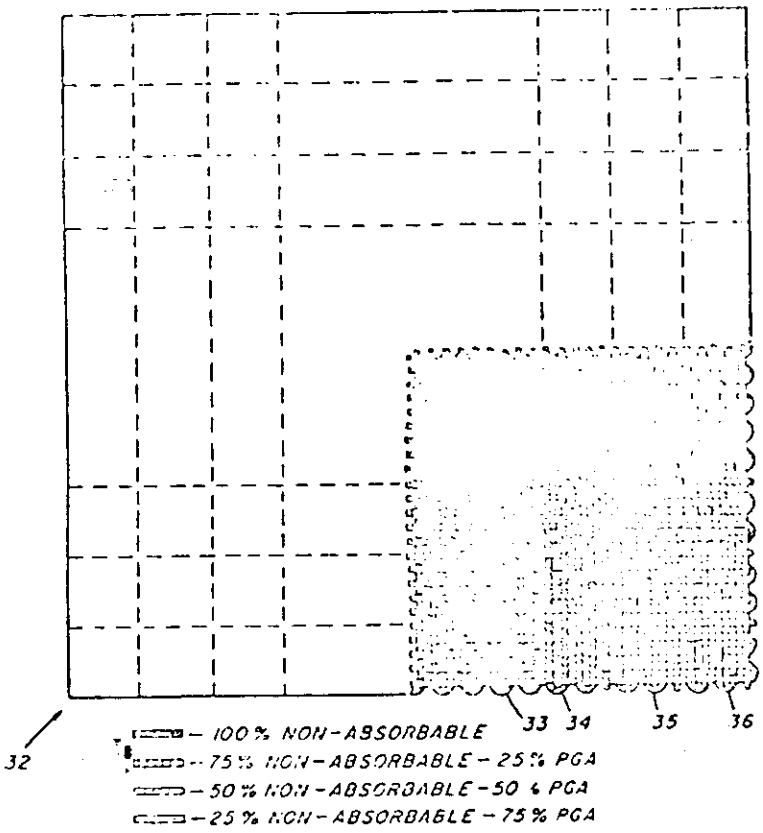


FIG - 3

INVENTORS
EDWARD EMIL SCHMITT
ROCCO ALBERT POLISTINA
BY
Samuel Brandstaft
ATTORNEY

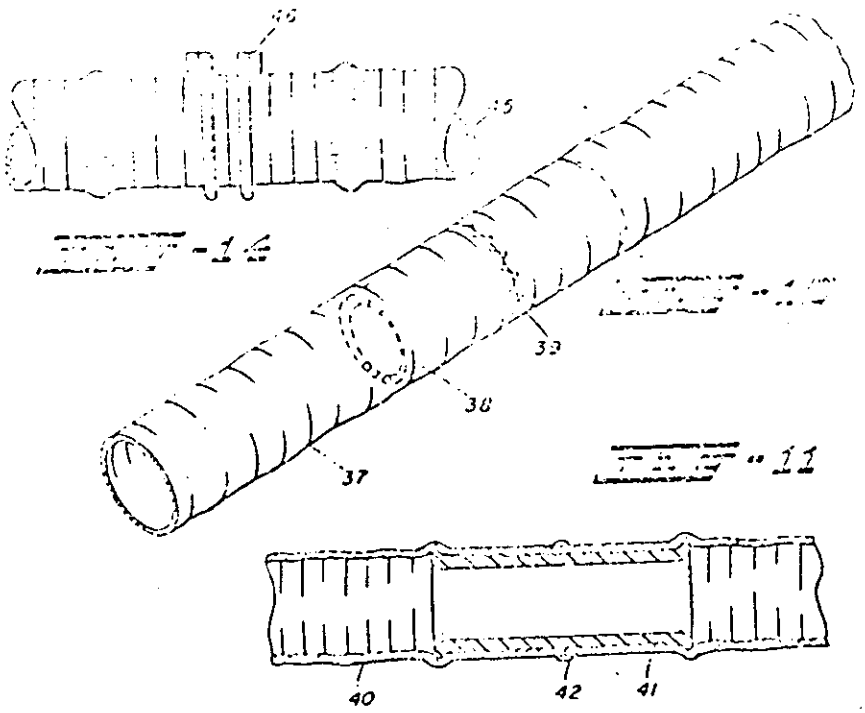


FIG -14

FIG -15

FIG -11

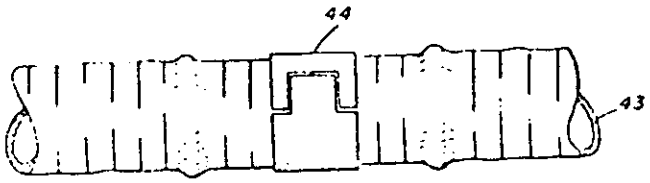


FIG -13

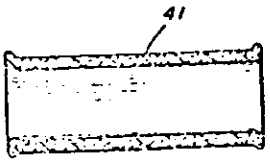


FIG -12

INVENTORS
EDWARD EMIL SCHMITT
ROCCO ALBERT POLISTINA
BY

ATTORNEY

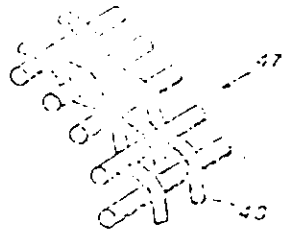


FIG - 14

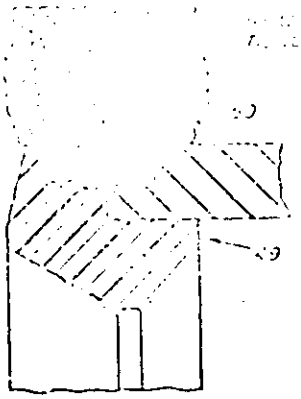


FIG - 15

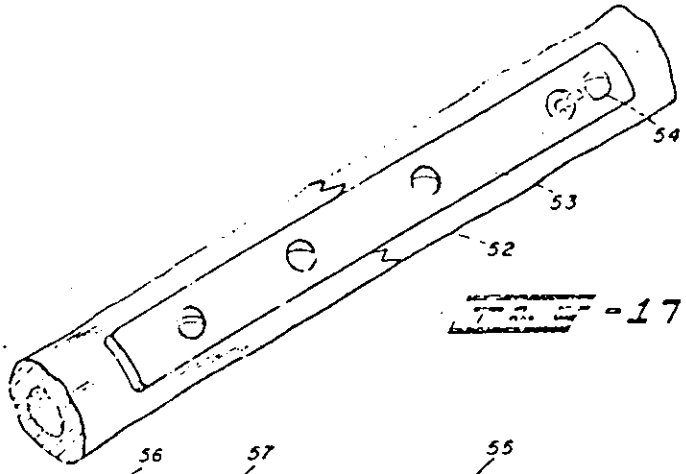


FIG - 17

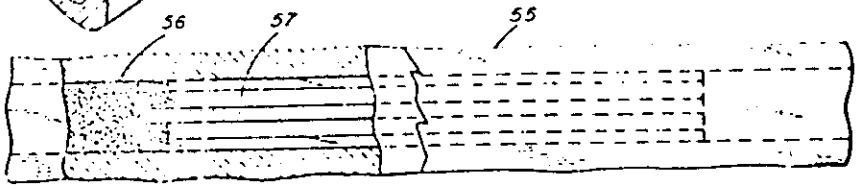


FIG - 18

INVENTORS,
EDWARD EMIL SCHMITT
ROCCO ALBERT POLISTINA
BY
ATTORNEY

[illegible]

U.S. Cl. 128—334 [illegible]

ABSTRACT OF THE DISCLOSURE

Polyhydroxyacetic ester, also called polyglycolic acid (PGA), [illegible] implantation, in living mammalian tissue, the polyglycolic acid is absorbed, and replaced by living tissue. Fabric structures of an intermixture of PGA and non-absorbable material are particularly useful in tissue repair or replacement so that living tissue mechanically unites about the non-absorbable fiber structure, locking it into place.

CROSS REFERENCES

This application is a continuation-in-part of application Ser. No. 320,543, filed Oct. 31, 1963 now U.S. Patent 3,297,033, Jan. 10, 1967, "Surgical Sutures."

Field of invention

This invention relates to absorbable surgical elements of polyhydroxyacetic ester hereafter called polyglycolic acid (PGA).

Prior art

The use of submucosal tissue and ribbons therefrom internally is described in such patents as United States Patent 2,167,251, Rogers, "Surgical Tape of Sumucosa Tissue," July 25, 1939, United States Patent 2,143,910, Didusch, "Ribbon Gut and Method of Using the Same," Jan. 17, 1939, and United States Patent 2,127,903, Bowen, "Tube for Surgical Purposes and Methods of Preparing and Using the Same," Aug. 23, 1938.

U.S.P. 2,836,181, J. S. Tapp, "Flexible Nylon Tube and Method for Preparing Same" shows a braided heat crimped formic acid treated nylon tube spliced into a blood vessel, with the crimp permitting a desired degree of flexibility.

U.S.P. 3,099,0[illegible], M. L. Edwards, "Heart Valve" shows a plastic cardiac valve, in which a fabric is emplaced in a ring around the valve, and sutured to the heart tissue, to permit the heart tissue to grow to such fabric, and hold the valve in position in the heart.

U.S.P. 3,054,406, F. C. Usher, "Surgical Mesh," Sept. 18, 1962, shows the use of a polyethylene woven mesh fabric implanted in the human abdominal wall for reinforcing and healing defects.

U.S.P. 3,108,357, W. J. Liebig, "Compound Absorbable Prosthetic Implants, Fabrics and Yarns Therefor" shows flexible fabrics of mixed absorbable and non-absorbable textile fibers for implantation, and reinforcement of tissue.

U.S.P. 3,124,136, F. C. Usher, "Method of Repairing Body Tissue," Mar. 10, 1964, shows the use of knitted linear polyethylene mesh attached to [illegible] defect. The polyethylene is [illegible] and permanently reinforces the tissue at the [illegible] of the defect. Additional details appear in Usher, [illegible] on Marlex Mesh in the Repair of [illegible] The American Surgeon 24, [illegible].

[illegible] surgical prostheses.

SUMMARY

[illegible]

A [illegible] a non-absorbable or absorbable material. It may be continuous or staple.

"Staple" is used to designate a group of shorter filaments which are usually twisted together to form a long continuous thread.

Non-absorbable surgically acceptable filaments include filaments of polyalkylenes, such as polyethylene, preferably linear polyethylene with a density of about 0.94 or higher, or polypropylene, preferably [illegible] polypropylene; or a polyamide, such as nylon; or a polyester, such as Dacron; or a polyacrylonitrile, such as Orlon or Creslan; or a halogenated polyalkylene, such as polytetrafluoroethylene, such as Teflon, or other halogenated polyalkylene, such as Kel-F or FEP; or cotton, or silk, or linen; or a metal such as stainless steel, tantalum, silver, gold, or platinum. The above are illustrative. Any non-absorbable material which is essentially inert in living mammalian tissue, particularly human tissue, is usable as a non-absorbable filament. Those materials having a comparatively high tensile strength and flexibility are preferred.

An absorbable filament is one which is absorbed, that is digested or dissolved, in living mammalian tissue.

A "thread" is a plurality of filaments, either continuous or staple, twisted together.

A "strand" is a plurality of filaments or threads twisted, plied, braided, or laid parallel to form a unit for further construction into a fabric, or used per se, or a monofilament of such size as to be woven or used independently.

A "bicomponent filament" is a filament composed of two separate materials. As used herein, the term is limited to a filament having one non-absorbable component and one absorbable component. The components may be adjacent. The most easily formed and preferred bicomponent filament is a sheathed filament with an internal non-absorbable material coated, or sheathed, approximately concentrically, with an absorbable component.

A "bicomponent thread" includes a thread of bicomponent filaments or a blend of different separate monofilament components twisted together, or both.

A "bicomponent strand" is a strand of one or more bicomponent filaments, or two different filament materials, or both, at least one component of which is absorbable.

A "bicomponent fabric" is a woven, knitted, felted, adhesively united, or otherwise formed [illegible] at least two [illegible] components, at least one component [illegible] absorbable.

A "coated fabric" is a fabric [illegible] with a [illegible] continuous [illegible] example by [illegible] [illegible] may be [illegible]

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[illegible]

[illegible] PGA is [illegible] useful in [illegible] PGA is completely dissolved in [illegible] leaves minimal or no residual scar tissue from the PGA.

A "gradual transition section" is a portion of bicomponent fabric, or bicomponent strand, which by selection of strands for the fabric, or components for the strand or strands, has a changing composition, over a short distance, of 1 mm. to 15 mm. or more, so that a fabric or strand changes in composition from non-absorbable material, or substantially non-absorbable material, to predominantly or completely absorbable material, whereby living tissue can replace the absorbable component and a gradual transition accomplished between the non-absorbable reinforcing prosthesis and the adjacent living tissue. With an arterial implant, for instance, a past cause of trouble has been the line of juncture between the implant and the natural artery wall. With a gradual transition, no sharp line of demarkation exists, and, hence, failures between the prosthesis and tissue are minimized. With implants of the types shown by Usher, supra, the edges of the reinforcing element could cause difficulties. With a gradual transition, a line of potential risk is eliminated.

For different purposes and in different types of tissue the rate of absorption may vary but in general an absorbable prosthesis should have as high a portion of its original strength as possible for at least three days, and sometimes as much as fifteen days or more, and preferably should be completely absorbed by muscular tissue within from forty-five to ninety days or more depending on the mass of the cross-section. The rate of absorption in other tissues may vary even more.

In common with many biological systems, the requirements are not absolute and the rate of absorption as well as the short-term strength requirement varies from patient to patient and at different locations within the body, as well as with the thickness of the section of PGA.

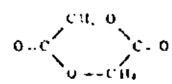
The PGA may be formed as tubes or sheets for surgical repair and may also be spun as thin filaments and woven or felted to form absorbable sponges or absorbable gauze, or used in conjunction with other structures as prosthetic devices, within the body of a human or animal where it is desirable that the structure have short-term strength, but be absorbable. The useful embodiments include tubes, including branched tubes or T's, for artery, vein or intestinal repair, nerve [illegible], tendon [illegible], sheets for tying up and supporting damaged [illegible], liver and other intestinal organs, protecting [illegible] surface areas such as abrasions, [illegible] areas where the skin and underlying tissues are damaged or surgically removed.

The synthetic character and hence predictable formability and [illegible] obtainable from a controlled [illegible]

[illegible]

[illegible] fed.

Among several methods by which PGA can be prepared, one preferred route involves the polymerization of glycolide,



the cyclic dimeric condensation product formed by dehydrating hydroxyacetic acid. During polymerization of glycolide, the ring is broken and straight-chain polymerization occurs.

Small quantities of other materials may be present in the chain, as for example, d-lactic acid, its optically active forms, homologs, and analogs. In general, plasticizers tend to interfere with crystallinity, orientation, etc. and weaken fibers, but are useful for sponges and films. Other substances may be present, such as dyes, antibiotics, antiseptics, anesthetics, and antioxidants. The surfaces of the fabric can be coated with a silicone, beeswax, and the like to modify the handling or absorption rate.

The polymerization of glycolide occurs by heating with or without a catalyst, or may be induced by radiation such as X-rays, gamma rays, electron beams, etc. Polymers may also be obtained by condensing glycolic acid or chloroacetic acid with or without a catalyst under a variety of conditions. Good moldable objects or fibers are most readily obtained when the melt viscosity at 245° C. is about 400 to about 27,000 poises.

Polyhydroxyacetic esters have been described in United States Patent 2,668,162, Lowe, "Preparation of High Molecular Weight Polyhydroxyacetic Ester," and United States Patent 2,676,945, Higgins, "Condensation Polymers of Hydroxyacetic Acid."

The processes described in the above two patents can be used for producing PGA from which prostheses may be made. Additives such as triphenylphosphite or Santo-Nox, a disulfide aromatic phenol, can be added as color stabilizers.

DRAWINGS

FIGURE 1 shows a [illegible] filament of [illegible] coated [illegible]

FIGURE 2 [illegible] filament [illegible]

FIGURE 3 [illegible]

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[illegible]

FIGURE [illegible] into a 75 [illegible] about [illegible] 25 [illegible]

FIGURE [illegible] percent [illegible] 50 [illegible]

FIGURE [illegible] sleeve with [illegible]

FIGURE 11 is a cross-section of [illegible] an internal sleeve with expanded ends.

FIGURE 12 shows a prosthetic sleeve formed of [illegible] tary coupling of solid polyglycolic acid with [illegible] pointing ends to aid in holding a blood vessel [illegible] the sleeve.

FIGURE 13 shows the sleeve of FIGURE 12 in use in which an external spring clip of solid polyglycolic acid holds the ends of the blood vessel together.

FIGURE 14 shows the sleeve of FIGURE 12 in which two expandable annular clips are used to hold the ends of the blood vessel approximated.

FIGURE 15 is a portion of a woven tube of cut [illegible] individual strands which are at least in part [illegible].

FIGURE 16 shows a portion of a heart valve [illegible] in heart tissue using a fabric in part composed of polyglycolic acid to aid in holding the valve in place.

FIGURE 17 shows a broken bone, the ends of which are held together by a solid bar of polyglycolic acid held to the bone by polyglycolic acid screws.

FIGURE 18 shows a broken bone, the ends of which are held in position by an internal fluted pin of polyglycolic acid.

PGA for the construction of the prostheses shown in the drawings can be produced as set forth in the following examples, in which parts are by weight, unless otherwise clearly indicated:

EXAMPLE 1

100 parts of recrystallized glycolide (melting point 85.0 to 85.5° C.) are intimately mixed with 0.02 part of methoxyacetic acid, 0.03 part of phenoldisulfide (Santo-Nox), and 0.03 part antimony trifluoride. Separate glass tubes are each charged with approximately 20 grams of the mixture, deoxygenated by repeated evacuation and argon purging, then sealed under vacuum and heated to 185 to 190° C. for 4½ hours. On cooling a white opaque tough PGA is produced in a 97.5% yield with a melt viscosity at 245° C. of 5,000 poises. The polymer is reheated and spun into filaments at a temperature of about 230° C. at a speed of about 150 feet per minute. The filaments produced are cooled, then drawn at about 55° C. When drawn to five times the original length a strong tough filament is produced. The dry filaments are in condition for use.

EXAMPLE 2

The polymer of the preceding example is formed into a plurality of smaller filaments, [illegible] twisted into a polyfilamentary strand, which [illegible] and used following the techniques of Example 1.

Because it is a synthetic polymer [illegible] ing are more versatile than [illegible] curring materials.

[illegible] in the [illegible] that the [illegible] of $SnCl_2 \cdot 2H_2O$.

[illegible] having a bore of about [illegible] is charged with 3 parts of the [illegible] glycolide composition, 0.01 part of $SnCl_2 \cdot 2H_2O$ [illegible] based on the weight of the substantially pure glycolide composition, 0.005 part of lauryl alcohol [illegible] based on the moles of the [illegible] composition, and a magnetic steel ball [illegible] in diameter. The tube is evacuated and purged with argon. The tube is evacuated again to a vacuum of less than 1 mm. of Hg and the top is sealed. The reaction tube is placed in a vertical position in a closed glass chamber throughout which dimethyl phthalate is refluxed at 222° C. The boiling point of the dimethyl phthalate is controlled by decreasing the pressure of the system. At periodic intervals after melting, the viscosity of the reaction mixture is measured by raising the steel ball by means of a magnet and measuring the rate of the fall of the ball in sec./in. Ninety minutes after the melt is first achieved, the ball drop time is 550 sec./in. or about 7200 poises, and after 120 minutes, the ball drop time is 580 sec./in. or about 7500 poises.

The PGA thus produced is spun into .002 inch diameter fibers and used to form bicomponent strands.

Additional PGA, similarly produced is used to coat Dacron filaments, in varying weight ratios to form bi-component strands which are braided into tubular arterial implants to splice into sections of arteries.

Additional PGA, similarly produced is used to form sheets. These sheets are wrapped around nerves, traumatically severed, to protect such nerves from invasive scar tissue growth, while the nerve is regenerating.

Also the PGA so produced is fabricated into the prosthetic devices shown in the drawings.

As is shown in the drawings, a bi-component filament 23 was formed by dipping a non-absorbable filament 21 of Dacron into a PGA melt forming a PGA coating 22 on the surface of the non-absorbable Dacron 21.

As shown in FIGURE 1 the dip was such that approximately 25% of the cross section was of Dacron and 75% of PGA.

In FIGURE 2 the structure is the same except that the relative proportions are changed to approximately 50% of each material.

In FIGURE 3 the structure is the same except that the proportions are [illegible] such that approximately 75% of the [illegible] is of Dacron and about 25% on the [illegible].

In FIGURE [illegible] filament is shown.

In FIGURE [illegible] of a bi-component [illegible] consists of 3 non-

[illegible]

It is to be [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible]

FIGURE 8 [illegible] [illegible] [illegible] with a 100% nonabsorbable [illegible] 33, [illegible] tion, and changing by 25% [illegible] 34, 35 until the [illegible] 25% nonabsorbable and 75% PGA.

Such a construction permits the [illegible] polyethylene or [illegible] polypropylene [illegible] tion of a repair patch, such as [illegible] in which gradation from the [illegible] sorbable material [illegible] spacing between the threads in the [illegible] for a particular application. [illegible] vice is to be used for the repair of [illegible] a comparatively widely spaced weave is desired. If used for an area in which liquid retention is critical, such as an artery or vein, the weave is much closer.

In FIGURE 9 is shown a knitted fabric 27, in which the respective strands are 100% nonabsorbable 28, followed by two rows of 75% nonabsorbable, 25% PGA 29 followed by two rows of 50% nonabsorbable 50% PGA 30, followed by two rows of 25% nonabsorbable 75% PGA 31.

In such a graded construction, the rate of change with distance or the number of rows of a particular composition are adjusted to fit the desired use. For smaller patches the width of each proportion of components is smaller than for large patches.

In FIGURE 10 is shown an artery 37 which is joined together over a tapered end PGA tube 38 which forms a stent about which the ends of the artery wall are joined by a suture splice 39. The tapered end is easier to insert in the artery.

In FIGURE 11 the artery walls 40 are joined together over a flared end PGA tube 41 and the ends are joined by a suture splice 42.

FIGURE 12 shows the flared end PGA tube 41.

In FIGURE 13 is shown a blood vessel 43, the ends of which are each separately placed over the end of a flared PGA tube and which blood vessel is held in place with the ends adjacent to permit healing by a PGA spring clip 44. PGA, such as produced in the above Example 3, shows an Izod impact strength of 0.14 ft. lb. per inch notch or greater. It may be heated and formed into a desired shape which shape is retained on cooling, and by shaping as a flat spring clip, can be used to hold together the walls of a blood vessel 43 until [illegible] takes place.

In FIGURE 14 is [illegible] splice of a blood vessel 45 but in which [illegible] together by an annular clip 46 of [illegible] PGA. [illegible] clips are well known for [illegible] arteries in animals [illegible] tubing to connect [illegible] of diameter and shape, as is well [illegible] provision at [illegible] to be [illegible] This is important [illegible] blood vessels and [illegible]

[illegible]

FIGURE 17 [illegible] 52 [illegible] PGA [illegible] 54.

FIGURE [illegible] PGA [illegible] 55 [illegible] PGA [illegible] pin 57 [illegible] to the bone marrow 56, the pins [illegible] of such size and shape as to fill the hollow in the bone and give mechanical strength and prevent motion at the break.

Absorbable splices or bone pins hold the bone in place until it has an opportunity to knit and then gradually dissolve. In the past metallic reinforcing elements have frequently been used. Such metallic elements add weight to the body, and perhaps cause inflammation by their physical presence [illegible] must be removed at a separate subsequent operation. Additionally, if a bone pin is used internally of a bone, the volume of bone marrow is materially reduced. When the PGA bone pin dissolves, no scar tissue remains and bone marrow is regenerated through the bone permitting the bone marrow to accomplish its organic functions.

The drawings above are illustrative only of embodiment of the present invention in which various prosthetic devices are incorporated into the human body to aid impaired functions of natural elements. From the above drawings and descriptions, it will be obvious to those skilled in the art that many other modifications may be adapted for particular injuries or ills to which the flesh is heir.

The finding that polyglycolic acid, abbreviated PGA, is absorbable in living tissue, and has marked mechanical strength, as a fiber or solid, including sheet, and hence can be used as an element in, or as, a surgical prosthesis, is most unexpected and unpredictable.

Catgut, or regenerated collagen has in the past been used for tissue emplacement, but with collagen, as the collagen is absorbed, a fibrotic tract replaces the collagen, so that in effect scar tissue remains at the site of the emplanted collagen for many years, in many instances for life. Some patients are allergic to collagen. PGA is not a protein, has no amino acids, and has given no evidence of allergic reactions in thousands of implants. With the present PGA prostheses, the PGA is completely absorbed, and a minimal or no trace of the inserted matter remains after a comparatively short period. This complete absorption, without residual fibrotic tissue, is unique, and an important contribution to surgery.

As it is obvious that examination of such prosthetic devices in humans must wait until autopsy, after death from natural causes, experimental results were conducted on laboratory animals which would permit sacrifice and examination at selected periods. These are shown in the following examples:

EXAMPLE 4

Absorbable intramedullary rod

[illegible] incisions were made on the [illegible] of the hind legs of anesthetized rabbits to expose the

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[illegible] at the end of [illegible], 12, [illegible] and 24 [illegible] the [illegible] which [illegible] were [illegible] examined. These [illegible] were [illegible] with [illegible] treated femurs which had [illegible] and Type [illegible] stainless steel [illegible] of [illegible] to those made of PGA.

With both the experimental and control animals the course of healing was uneventful. The [illegible] were essentially healed by the [illegible] week. After [illegible] the femurs were [illegible] longitudinally and the effect of time on the implants were observed. As expected in the [illegible] short times used the stainless steel pin was essentially [illegible] but since the internal space was largely occluded where the metallic pin was present, there was no marrow tissue.

Where the medullary rod of polyglycolic acid had been used, at six weeks the overall structure of the rod was essentially unchanged but there were fissures developing on the surface and the cut ends which had been sharply defined were somewhat rounded. The rod was somewhat softened on the surface. There was a progressive increase in the amount of erosion of the PGA rod [illegible] but this erosion was never associated with inflammation or other adverse reactions. By the 24th week the rod of polyglycolic acid was essentially digested and the bone now showed normal tissue architecture.

EXAMPLE 5

Absorbable bone plate affixed with absorbable pins

Femurs of the hind legs of rabbits were [illegible] as described in Example 4. The cut ends were reapproximated and immobilized by use of an internal [illegible] made from a sheet of polyglycolic acid approximately [illegible] inch thick [illegible]" wide and 1 inch long, shaped to conform generally to the bone by softening the plastic with heat and premolding it about a metal rod of suitable diameter. The premolded plate was centrally located over the cut bone and while held in position, small holes were drilled through the plate and completely through the bone with a [illegible] inch drill, two holes on each side of the bone break. Small PGA nails about [illegible] inch long and slightly over [illegible] inch in diameter made by flattening rod of this diameter by pressing against a heated surface were driven through the holes in the PGA plate and completely through the bone to hold the plate in place. The soft tissue was reapproximated, the broken legs splinted and the animals were returned to their cages. X-rays were taken weekly and animals were sacrificed at 3, 6, 12, 18 and 24 week intervals. The legs which [illegible] were operated [illegible] were carefully [illegible] to determine the fate of the [illegible] cells and [illegible] to [illegible] the course [illegible]. At 3 weeks the bone was [illegible] PGA implant was [illegible]. By [illegible] break [illegible] bone was healed [illegible] PGA [illegible]

[illegible] In this example where the arterial prostheses were to be used in rabbits, the tubes were only [illegible] in diameter.

The abdominal aorta was exposed by incision through the ventral wall, two clamps separated by about [illegible] inches were placed on the abdominal aorta just distal to the renal artery. The approximately 1 inch of the abdominal aorta between the clamps was resected and a comparable length of prosthetic tubing made as described above was sewn in place. The clamps were removed, and the animal was observed closely until blood seepage had stopped. The abdomen was then closed and the animal returned to its cage. Sacrifices were made at the end of 1, 3, 6, 12, and 18 weeks and the prosthetic implant and the neighboring tissue was examined. After the first week there was little change in the prosthesis. The pores of the fiber were closed with fibrin and some new cell growth was noticeable at the cut ends of the blood vessel. By three weeks the fibrin clots had been partially replaced by new cells which represented the partial development of a pseudo intimal lining extending from the ends of the original vessel. The polyglycolic acid filaments were still intact but were showing [illegible] of surface erosion on microscopic examination. By 6 weeks the pseudo intimal lining was complete. Blood vessels were beginning to develop in this tissue layer. Growth of cells was occurring through the pores of the prosthesis which were now substantially enlarged by the obvious diminution in size of the PGA filaments which were no longer continuous. Shredding of the PGA filaments was evident but the complete development of the pseudo intima prevented the shreds from entering the blood stream where they could represent foci for clot formation. By the twelfth week the PGA was essentially replaced by tissue elements which formed a well vascularized multicelluar layer completely capturing the polyester filaments of the prosthesis. The picture at 18 weeks was similar to that at 12 weeks with more vascularization and greater organization of the cells of the inner lining and outer surface of the prosthesis. There was a conspicuous absence of any inflammatory response or abnormal tissue reaction. The absorption of the polyglycolic acid gave sufficient space in the fiber network to permit adequate cell growth and proper vascularization so that necrosis of tissue did not develop.

So far as inspection permits, similar results appear to be obtained in humans. Of course with humans, and larger animals proportionately sized prostheses must be used.

We claim:

1. A surgical prosthesis comprising non-absorbable filaments shaped as a [illegible] reinforcing element, and [illegible] said non-absorbable filaments, in at least a part of the element, a structure consisting essentially of polyglycolic acid, whereby on implantation in living [illegible], the polyglycolic acid structure is